APPEAL TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:	
Luc MONTAGNIER et al	Group Art Unit:
Application No.: 08/470,489	Examiner: Parkin, J.
Filed: June 6, 1995	
For: RETROVIRUS CAPABLE OF CAUSING AIDS, MEANS AND METHOD FOR DETECTING IT *IN VITRO*	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

SUPPLEMENTAL REPLY BRIEF
ON APPEAL UNDER 37 C.F.R. § 1.193(b)(1)

In response to the Supplemental Examiner's Answer dated January 20, 2004, and pursuant to 37 C.F.R. § 1.193(b)(1) allowing for a reply brief to a Supplemental Examiner's Answer, Appellants submit the following remarks.

REMARKS

I. Issues Resolved by Examiner's Answer

In the Supplemental Examiner's Answer dated January 20, 2004, the Examiner stated: "[t]he statement of the status of the claims contained in the brief is correct"; "[t]he appellants' statement of the status of amendments after final rejection contained in the brief is correct"; "[t]he summary of invention contained in the brief is correct"; "[t]he appellants' statement of the issues in the brief is correct"; and "[t]he copy of the

appealed claims contained in the Appendix to the brief is correct." (Supplemental Examiner's Answer, at 2-3.) Accordingly, the Examiner does not dispute the accuracy of these sections of the brief, or the statements contained therein. Thus, Appellants request that the Board adopt the statements in each of these sections.

II. Written Description Rejection

In the Supplemental Reply Brief, the Examiner has now summarized the rejections and responded to Appellants' arguments.

A. Application of *Enzo Biochem, Inc. v. Gen-Probe Inc.*

The recent Federal Circuit case, *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956 (Fed. Cir. 2002) considered under what specific circumstances functional language could support the written description. In that case, the claims were directed to nucleic acid probes that selectively hybridize to the DNA of *Neisseria gonorrhoeae*, when compared to a similar bacteria *Neisseria meningitides*. The patentee, Enzo, had identified three nucleic acid probes meeting the claim limitations and had deposited those probes. Enzo argued that the claims were supported by the written description because of the disclosed correlation of the function of hybridization with the bacterial DNA. Id. at 967. As strains of the two bacteria were publicly available and could be used to identify which probes would meet the limitations of the claims, the Federal Circuit stated that whether the claims were supported by the written description was a factual one and could not be decided against the patentee in summary judgment. In

doing so, the Federal Circuit relied on the Written Description Guidelines issued by the U.S.P.T.O. The Guidelines state that written description can be met by

> Show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics . . . i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.

Id. at 964 (quoting Guidelines, 66 Fed. Reg. at 1106).

The Federal Circuit continued by describing an example provided in the guidelines of claims to an isolated antibody to a known antigen, given the well defined structural properties of antibodies, the functional characteristics of antibody-antigen binding, and the high level of scientific understanding in that particular field. *Id.* It concluded, before remanding the case, that the written description requirement would be met for all of the patent claims "if the functional characteristic of preferential binding to *N. gonorrhoeae* over *N. meningitidis* were coupled with a disclosed correlation between that function and a structure that is sufficiently known or disclosed." *Id.* The Federal Circuit continued by stating "[b]ecause the claimed nucleotide sequences preferentially bind to the genomic DNA of the deposited strains of *N. gonorrhoeae* and have a complementary structural relationship with that DNA, those sequences, under the PTO Guidelines, may also be adequately described." *Id.* at 968.

Thus, the court remanded the case to determine "whether a reasonable fact-finder could conclude that the claimed sequences are described by their ability to

hybridize to structures that, while not explicitly sequenced, are accessible to the public. Such hybridization to disclosed organisms may meet the PTO's Guidelines stating that functional claiming is permissible when the claimed material hybridizes to a disclosed substrate." *Id.*

Like *Enzo*, in the present case the specification describes a number of probes for use in the invention and the Examiner has acquiesced on this point.1 Additionally, Applicants have indicated that the probes will hybridize to HIV-2_{ROD} genomic DNA under particular recited hybridization conditions. The HIV-2_{ROD} genomic DNA is available and the Examiner has also agreed that Appellants have provided "detailed nucleotide sequence data,"[2] just as the bacterial strains were in *Enzo*—providing a known structural feature to which the probes can be hybridized to. Thus, both cases claim probes (*Enzo*) or methods of using the probes (this application) that hybridize to publicly available bacterial strains (*Enzo*) or virus DNA sequences (this application). This combination of structural and functional features having a disclosed correlation between that function and a sufficiently described structure is sufficient to provide written description support for this invention.

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1 HIV-2ROD probe E2/pSPE2 corresponding to the U3/R LTR region (380 nt); ROD *gag* gene, nt. 1-405; 406-1155; 1156-2574 and ROD *env* gene, nt. 1-2574 (Supplemental Examiner's Answer, at 4 and 5).

2 The Examiner agrees that detailed nucleotide sequence data was provided from subgenomic HIV-2ROD clones. (Supplemental Examiner's Answer at 4).

The Examiner objects to the fact that "[t]he probes employed are not directed toward any specific nucleotide sequence or any particular length." Supplemental Examiner's Answer, at 4. However, Applicants also wish to point out that the claimed probes in *Enzo* were similarly not restricted to a particular length, nor were they fragments of a specified nucleic acid sequence. Claim 1 was not limited to completely complementary sequences and no source of nucleic acid was identified for the probes, nor were they specified as having a particular length. Similarly, in *Enzo*, claim 4 recited nucleic acid probes derived from a particular sequence as well as mutants and variants of those probes. *Id.* at 961-62. While the Federal Circuit noted that this increased the number of probes falling within the claimed invention, it also acknowledged Enzo's statement that "such broad claim scope is necessary to adequately protect Enzo's invention from copyists who could otherwise make a minor change to the sequence and thereby avoid infringement while still exploiting the benefits of Enzo's invention." *Id.* at 966. The court, again, concluded that this was a factual issue, but did acknowledge Enzo's statement that without reasonable breadth probe claims would be of limited utility.

On pages 7-8 of the Supplemental Examiner's Answer, the Examiner cites to the relevant portions of the *Enzo* decision, but fails to apply the law to the facts of this case. The Examiner ignores the fact that the probes used in the claimed method have a functional relationship to HIV-2_{ROD} genomic DNA, the sequence of which has been

disclosed. Applicants wish to draw the Board's attention to the similarity between the facts of the present case and *Enzo* and request that the rejection be withdrawn.

B. Issues regarding the Melting Temperature

In the Supplemental Answer, the Examiner focuses on the melting temperature T_m of the probes used in the claimed methods. The Examiner has correctly stated that the melting temperature of a duplex is simply defined as the temperature when half of the duplex molecules have dissociated in to their constitutive single strands.

The Examiner then states, however, that "merely reciting limitations vis-à-vis the T_m fails to provide any significant structural guidance pertaining to the actual probe employed." Examiner's Supplemental Answer, at 6. Appellants do not rely on the melting temperature limitations to structurally define a probe with a particular melting temperature. Instead, the melting temperature refers to the conditions under which the probe hybridizes to HIV-2_{ROD} genomic DNA and is also used in the other method processes described.

Specifically, the probe should hybridize to the HIV-2_{ROD} DNA under conditions selected from 42°C below the melting temperature of the probe, 20°C below the melting temperature of the probe, and 3°C below the melting temperature of the probe. The melting temperature of any given nucleic acid probe is very easy to determine. As the Examiner stated "[i]t is well-known in the art that the melting temperature (T_m) of any given duplex is simply defined as the temperature when half of the nucleic acid duplex

molecules have dissociated in to their constitutive single strands." Supplemental Examiner's Answer, at 5.

Thus, one need only take the probe in question and its 100% nucleic acid complement, to determine the melting temperature of the probe. One skilled in the art would realize that the T_m should be determined under the same hybridization conditions under which the probe will be tested for hybridization to HIV-2_{ROD} and the test sample. Therefore, the percent formamide and other experimental conditions (such as solvent and pH) should be the same in the T_m determination as in the two hybridization reactions. Therefore, it is not necessary to specify these variables in the claim, as long as the variables are being held constant through the determination of T_m and the two hybridization experiments.

Additionally, Applicants wish to point out that claim 1 considered in *Enzo* recited hybridization conditions based on T_m, as well. In claim 1, the hybridization conditions were recited as 2X SSC, 65 C for probes shorter than 50 bases and T_m-30 C for probes longer than 50 bases. *See Enzo*, 323 F.3d at 961. No where in the Federal Circuit opinion was reliance on T_m criticized by the court. Like the present case, *Enzo* focused on comparing hybridization of a given probe to one sample versus another sample. One skilled in the art would understand that so long as the conditions remained the same between experiments, with the only variable being the sample tested, a range of hybridization conditions could be used.

C. Status of the Claims as Method Claims

Applicants withdraw the arguments regarding the status of the claims as method claims in light of the recent Federal Circuit decision stating that the standard for written description support of a composition claim or a method claim using that composition is the same. *See University of Rochester v. G.D. Searle & Co., Inc.*, No. 03-1304, slip op. at 17 (Fed. Cir. Feb. 13, 2004).

III. CONCLUSION

In view of the foregoing remarks, Appellants respectfully submit that the rejection of claims 90-109 under 35 U.S.C. § 112, first paragraph, is in error and should be reversed.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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